Attachment

Instructions and Formats
STANDARD CANCER CENTER INFORMATION SUMMARIES
September 2003

A fundamental set of information referred to as the Standard Cancer Center Information summaries should be included in all competing and noncompeting continuation CCSG applications. The summary information is important to ensure the consistency and thoroughness of peer review of competing applications; it is also important to the NCI's Cancer Centers Administrative Profile Database used to produce summary reports on the Cancer Centers Program. Summaries to be submitted, by application type, are as follows:

Code	Type of Application	Summaries to be Submitted
Type 1 or 1A	New Competing or Amended	1, 2, 3, and 4
Type 2 or 2A	Competing Renewal or Amended	1, 2, 3, 4, and 5
Type 3	Administrative Extension with Funds	Consult Program Director
Type 5	Non-competing Continuation	1, 2, 3, and 4

In addition to including summary information in competing and non-competing continuation applications, Centers are required to submit an electronic copy of their summary information directly to the Cancer Centers Branch. The electronic version of the summaries should be submitted at the same time as the application. Summary information may be sent electronically as an email attachment to either of the email addresses shown below. The format of the electronic files must be compatible with the Cancer Centers Branch database.

winklerp@mail.nih.gov
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General Instructions: Below are general instructions for summary submissions. Instructions specific to each summary follow, along with example formats.

1. Insert the full grant number (i.e. 1P30CA000000-01) in the upper right corner of each page.
2. Label summaries consistently (i.e. 1A, 1B, 1C).
3. The reporting period should be the most recent 12 month period possible. The same reporting period should be used for all summaries to the greatest extent possible.

SUMMARIES 1A, 1B, 1C, and 1D
Cancer Center Senior Leaders, Research Programs, Members, and Shared Resources

INSTRUCTIONS

1. Using the example format for Summary 1A as a guide, list names, titles, and academic degree(s) of the senior leadership of the Center (e.g., Cancer Center Director, Associate Directors, Center Administrator, etc.). If a leader has changed since the prior year submission, indicate the change with an asterisk next to the new leader's name.

2. Using the example format for Summary 1B as a guide, provide the information requested for each established research program of the cancer center, listing the name of the program, the name and academic degree of the Program Leader, and the number of members in the program. If a leader has changed since the prior year submission, indicate the change with an asterisk next to the new leader's name. A unique reference code (e.g., 01, 02, etc.) should be assigned to each program in this table (for use on Summaries 2 and 4). Developing programs may be included, but should be clearly identified as "developing." A special code ("ZY") also should be assigned for non-programmatically aligned members. This code will identify projects (Summary 2) and trials (Summary 4) conducted by researchers who are non-aligned members. Do **not** list individual members of programs in this section.

3. Using the example format for Summary 1C as a guide, provide the total number of programmatically aligned members, the total number of non-programmatically aligned members, and the grand total of all center members. Provide only the information requested.

4. Using the example format for Summary 1D as a guide, list the full name of the shared resources of the cancer center, the name and academic degree(s) of the resource director, and select one or more categories for each shared resource from the list entitled "Categories of Shared Resources." Do not include shared resources that are **not** supported by the CCSG. Developmental cores may be included, but should be clearly identified as "developing."

Summary 1A - Example Format
Senior Leadership

2P30CA654321-50

Outstanding University Cancer Center

reporting period 1/1/2002 - 12/31/2002

Name of Senior Leader	Title of Leader	Degree(s)
Sutton, Baylor D.	Principal Investigator	M.D., Ph.D.
Marucco, Gina L.	Deputy Director	Ph.D.
Galley, Mark E.	Assoc. Director for Basic Science	M.D.
Barrie, Thomas X.	Assoc. Director for Clinical Research	M.D., Ph.D.
Wong, Lee R.	Assoc. Director for Population Research	Ph.D.
Young, Jenni Jo	Assoc. Director for Administration	MHA

Summary 1B - Example Format
Research Programs, Leaders, and Codes

2P30CA654321-50

Outstanding University Cancer Center

reporting period 1/1/2002 - 12/31/2002

Program Code	Program Name	Program Leader(s)	Total # Members (including leader)
01	Molecular and Cellular Biology	Harrington, Marc, M.D, Ph.D.	25
02	Genetics (developing)	Lee, David, M.D.	38
03	Cancer Prevention Research	Pham, Phuong T. K., Ph.D.	14
04	Epidemiology	Kaufman, Richard, M.D., Ph.D.	19
05	Cell Cycle and Growth Control	Neuhauser, Beverly N., M.D.	12
06	Immunology	*Bhorjee, Jaswant, M.D., Ph.D.	27
ZY	Non-Aligned Members	N/A	12

Summary 1C - Example Format
Cancer Center Membership

2P30CA654321-50

Outstanding University Cancer Center

reporting period 1/1/2002 - 12/31/2002

Type of Member	Total Number
Programmatically Aligned Members (Individuals)	135
Non-Programmatically Aligned Members (Individuals)	12
Grand Total - Total Number of Center Members (Individuals)	147

Summary 1D - Example Format
Shared Resources

2P30CA654321-50

Outstanding University Cancer Center

reporting period 1/1/2002 - 12/31/2002

Name of Shared Resource	Resource Director(s)	Category
Biostatistics	Francini, Benjamin, Ph.D.	6.01
DNA Microarray (developing)	Poole, Bruce D., M.D.	1.35
DNA Sequencing	Kelley, Steven, S., M.D., Ph.D.	1.22
Genomics and Proteomics	Goldstein, Phillip, M.D.	1.36
Bioinformatics	Mayrend, Jody, Ph.D.	7.02
Organic Synthesis	Singer, Richard, F., M.D., Ph.D.	1.12
Transgenic Animal Facility	Peterson, Douglas, M.D. / Barns, Nancy, M.D.	1.03, 1.06 ,1.09

Categories of Shared Resources

Assign each shared resource with the appropriate 3-digit number (maximum of three codes) to indicate the applicable categories and subcategories.

Category 1: Laboratory Science
Subcategories
1.01 Biochemical Analysis
1.02 General Animal Facility
1.03 Transgenic Facility
1.04 Special Breeding
1.05 Animal Health (Pathology/Histology)
1.06 Animal Health (QC)
1.08 Specific Pathogen Free (Barrier Animal Facility)
1.09 Nude Mouse
1.10 Specialized Animal Svcs (Irradiation)
1.11 Biohazard Control
1.12 Organic & Synthetic Chemistry
1.13 Chromatography
1.14 Cytology-Analytic & Immunologic
1.15 Cytogenetics
1.16 Genetics
1.17 Electron Microscopy
1.18 Flow Cytometry
1.19 Cyclotron or Radiolabeling
1.20 Molecular Biology
1.21 Nucleotide Sequencing
1.22 Protein & Peptide Sequencing
1.23 Monoclonal Antibodies
1.24 NMR
1.26 MRI
1.27 Spectrometry, Other (Specify)
1.28 Radiobiology
1.29 Oligonucleotide Synthesis
1.30 Protein/Peptide Synthesis
1.31 Toxicology/Mutagenesis Testing
1.33 Confocal Microscopy
1.34 Xray Diffraction
1.35 DNA Array
1.36 Proteomics
1.37 Other (Define)

Category 2: Laboratory Support
Subcategories
2.01 General or Equipment Repair
2.02 Machine Shop
2.03 Glassware Washing
2.04 Illustration/Photography/Typeset
2.07 Tissue Culture
2.08 Media Preparation
2.10 Other (Define)

Category 3: Epidemiology, Cancer Control
Subcategories
3.01 Cancer Control
3.03 Epidemiology
3.04 Survey
3.05 Nutrition
3.06 Other (Define)

Category 4: Clinical Research
Subcategories
4.02 Clinical Trials Protocol Management & Data Management
4.03 Clinical – Other
4.04 Pharmacology (Animal)
4.05 Pharmacology (Lab Tests)
4.06 Human Tissue Acquisition & Pathology/Histology
4.07 Gene Therapy/Vector
4.08 Other (Define)

Category 5: Administrative
5.01 Secretarial/Word Processing

Category 6: Biostatistics
6.01 Biostatistics

Category 7: Informatics
Subcategories
7.01 Clinical Research Informatics
7.02 Bioinformatics
7.03 Public Health/Epidemiology Informatics
7.04 Other (Define)

Category 8: Miscellaneous
8.01 (Define)

SUMMARY 2A
Active Funded Projects

INSTRUCTIONS

Following the example format for Summary 2A, list all of the active, funded, cancer-relevant projects competitively awarded by external sources to the parent institution (i.e., for matrix centers, the fiscally responsible institution of which the cancer center is a part). If more than one institution is an integral part of the cancer center (see CCSG Guidelines, Part I, 3.0 and Part II, 2.1.3), provide a Summary 2 for each institution.

1. This is to be a complete list in two parts:

    - active funded *research projects* in alphabetical order by Principal Investigator's last name; and

    - *training and career development* grants in alphabetical order by Principal Investigator's last name.

2. This list should **not** be differently sorted or grouped, such as by research Program or funding agency, except as a secondary sorting if desired.

3. The date of preparation should be noted in the upper right hand corner of the page and the list of funded projects in this summary should reflect all active projects at the cancer center as of the date of preparation of the report. The reporting period should also be listed on the first page of the summary.

4. For each project, list the Principal Investigator (PI); funding source (e.g., NCI, NIAID); complete project number with prefix and suffix showing the current grant year (e.g., 5R01 CA012345-06, 2N01CA654321-12); full project period (e.g., 1 yr:1/1/00-12/31/00; 3 yr:1/1/05-12/31/07; 5 yr:1/1/01-12/31/06, etc.) and the full project title.

5. Identify the CCSG approved research program(s) to which each project belongs in the "prog code" column using the codes from Summary 1B. For individual projects split among two or more research programs, list the grant in separate records for each program code to which the project is assignable, with the code in the "prog code" column, and the proportion attributable to the program in the "%" column. List once, in the first record only, the total direct costs of the grant in the "Direct Cost" column and the total costs (direct plus indirect) in the "Total Cost" column. For the last two columns, and for each record, calculate the proportional amounts of direct and total costs attributable to the program. The ***Dubois, Y.*** grant in the example format demonstrates how a split project is to be handled. Note: For National trials coordinated by your center, indicate only the direct and total costs for work performed at your center.

6. The sum of the percentages and dollars of any project assigned to different programs should not exceed 100%. However, there may be situations in which only part of a

project is carried out within the cancer center, in which case only the cancer center portion should be shown, and the total percentage for such a project will be less than 100%.

7. For other types of projects, use a miscellaneous category "ZY" to list any funded research projects not carried out as part of a formal program and/or any projects or parts of projects that have not otherwise been assigned to approved research programs. The category "ZY" should be used for all other miscellaneous project assignments, such as instrumentation grants, cores, or a Cancer Information Service contract. **List the cancer center support grant itself under a separate category labeled "ZC."**

8. For each project provide the direct costs and total costs (direct and indirect) funded for the current year. If an award consists of multiple projects (i.e. a P01 or SPORE), then each assignable project should be listed with the name of the PI/name of the project leader as shown in the example format. Administrative support provided by the P01 "administrative core" may be assigned to the appropriate program or to the miscellaneous category "ZY." Follow the example format for P01 subprojects and Principal Investigators of the subprojects.

9. Using the same procedure as above, list all training awards and research career development awards at the end of Summary 2A in a separate section following a subtotal of the research grants. Identify all training grants with the code "**T**," regardless of the source or type, including the F, K and T series NIH grants. Provide a subtotal of the training grants (if any) and a grand total of all grants.

Outstanding University Cancer Center

reporting period 1/1/2002 - 12/31/2002

RESEARCH PROJECTS

PI	Funding Agency	Grant #	Start Date	End Date	Proj Title	Dir Cost	Tot Cost	Proj Code	%	Proj Dir	Proj Tot
Alfred, L.	NIH	5R01DK059736-04	06/05/95	04/30/05	Regulation of mitochondrial inheritance in yeast	197713	342043	4	100	197713	342043
Blake, J.	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Program Director)	1116373	1931325				
Blake/Maleck	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Admin Core A)			5	100	235034	381460
Blake/Tillis	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Pharm Core C)			4	100	89579	146506
Blake/Guzic	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Hem Onc Proj. 1)			2	100	280531	485088
Christy, W.	ACS	RPG-96-045-04-1	01/01/98	06/30/04	The role of an HNF-3 protein in c elegan foregut development	103537	128921	2	100	103537	128921
Dubois, Y.	NCI	5R01CA067893-02	09/08/97	06/30/03	Star trial (Tamoxifen vs. Raloxifene)	97784	165288	1	50	48892	82644
Dubois, Y.	NCI	5R01CA067893-02	09/08/97	06/30/03	Star trial (Tamoxifen vs. Raloxifene)			5	50	48892	82644
Gehr, A.	NCI	5N02C654321-09	04/01/01	05/31/06	Cancer Information Service	1421931	1766530	ZY			

Eutto, M.	NCI	5R01CA083747-03	12/27/00	11/30/02	Genetic epidemiology of breast cancer--BRCA1 and BRCA2	146128	252801	6	100	146128	252801
Royce, R.	NIH / Subcontract Univ.	5R01HL086850-04	08/01/02	06/30/04	Calpain and p120 catenin regulation of cadherin function	33333	55333	3	100	33333	53333
Sutton, B.	NCI	5P30CA011189-11	12/01/01	11/30/02	Core Grant	3439815	3760687	ZC			
			Research Subtotals:			6,556,614	8,402,928			1,183,639	1,955,440

TRAINING PROJECTS

PI	Funding Agency	Grant #	Start Date	End Date	Proj Title	Dir Cost	Tot Cost	Proj Code	%	Proj Dir	Proj Tot
Adams, Q.	Army	DAMD1702-1-11	09/01/02	08/31/04	Molecular study of bag domains: A new motif in prostate cancer	45368	48997	T	100	45368	48997
Burns, W.	NCI	5T32CA009579-01	05/01/87	02/28/04	Cell adhesion and effects on cell behavior	23470	25345	T	100	23470	25345
Carolan, R.	NIH	F32HL069595-02	07/01/01	06/30/05	Differentiation of a stem cell population in vivo	35585	35585	T	100	35585	35585
Dicenza, R.	NIH	K08MH001711-02	07/01/99	06/30/04	Serotonergic mechanisms is stress and anxiety	164882	178071	T	100	164882	178071
			Training Subtotals:			269,305	287,998			269,305	287,998
			Grand Totals:			6,825,919	8,690,926			1,452,944	2,243,438

SUMMARY 2B
Summary of Active Funded Projects

INSTRUCTIONS

Provide the information requested which summarizes the number and type of grants and contracts listed on Summary 2A. List the total number of projects, the sum of direct costs and the sum of total costs (direct plus indirect) for each major funding agency category as follows: NCI, other NIH, ACS, NSF, other Peer Reviewed (as defined by NCI in Part II, 3.1.1 of the CCSG guidelines) and Non Peer Reviewed (Industry-sponsored and Other). Provide subtotals where indicated and a grand total for all projects.

Summary 2B – Example Format 2P30CA654321-50

Summary of Active Funding

Outstanding University Cancer Center

reporting period 1/1/2002 – 12/31/2002

Funding Agency	Total Number of Projects	Sum of Direct Costs	Sum of Total Costs (Dir+Indir)
NCI	20	5,579,706	9,085,388
Other NIH	47	9,446,080	14,851,293
ACS	2	80,000	80,000
NSF	5	666,030	1,087,092
Other Peer Reviewed*	9	6,420,432	6,967,926
Subtotal of Peer Reviewed	***83***	***22,192,248***	***32,071,699***
Industry Non Peer Reviewed	35	3,299,571	3,544,740
Other Non Peer Reviewed	30	4,013,038	5,472,172
Subtotal of Non Peer Reviewed	***65***	***7,312,609***	***9,016,912***
Grand Total (All Projects)	148	29,504,857	41,088,611

SUMMARY 3
Reportable Patients/Accrual to Therapeutic Protocols
By Anatomic Cancer Site

Background and Definitions

This section requests summary information about the numbers of cancer patients treated at the cancer center. Do not include individual patient identifiers. The information is intended to convey an idea of what kind of cancer patients are being treated at the cancer center and how well the cancer center is doing in accruing patients to clinical trial protocols. It bears in a broad sense upon the reviewers' consideration of the clinical research activities of the cancer center.

It is important that the centers adopt a uniform policy regarding which patients are reported. This will ensure that the descriptions of the patient populations at the various centers are consistent, accurate and comprehensive. It would make little sense if one center were to submit data only on highly selected groups enrolled in specific protocol studies, while another reported on any cancer patient who received diagnostic or therapeutic services at the center. The following definitions are intended to clarify which data are to be reported.

Reporting Period: The 12-month period for which data are being provided for Summary 3. This period should be consistent with the reporting period used in Summaries 1, 2, and 4 to the greatest extent possible.

Reportable Cancers: Determination of whether or not a given primary tumor is reportable is made by reference to the morphology codes (M-codes) of the International Classification of Diseases for Oncology (ICD-O). In addition to a four digit specification of the particular histologic type of the tumor, these codes contain a fifth digit to describe its pathologic behavior, as follows:
0 - Benign
1 – "Borderline," uncertain whether benign or malignant
2 - Carcinoma in-situ
3 - Malignant, primary site

Cancers which are reportable are all those for which the fifth digit of the M-code terminates in "2" or "3." Cases of superficial basal and/or squamous cell neoplasms of the skin (i.e., ICD-O codes T-173 with M-8050 through M-8110) are not to be reported. Thus, the system includes only primary tumors which are frankly malignant, excluding benign neoplasms and those of borderline malignancy.

Reportable Patients: Reportable patients are those seen face-to-face and registered at the cancer center, whether as inpatients or outpatients, during the reporting period. All patients registered should be counted regardless of whether they have a newly diagnosed cancer or have recurrent disease and were referred to the cancer center for further evaluation and primary or secondary treatment occurring after the start date of the reporting period. This category excludes consults (e.g., for service or second opinions), diagnoses at autopsy, and former patients admitted for rehabilitation purposes or treatment of some other conditions. It also excludes patient follow up activities after treatment is completed.

The question as to which patients are reportable is closely related to the cancer center's self-definition, and it is recognized that this varies considerably from place to place. In some cases the center is synonymous with a single institution which specializes in the diagnosis and treatment of cancer; other centers consist of the cancer units within a larger hospital, such as a university medical hospital, in which patients having many different diseases are seen; and for still others the cancer "center" involves a consortium of hospitals or institutions which have developed an integrated cancer program. For centers which are limited to a single hospital, whether or not it specializes in cancer, a reportable patient is an individual with a reportable cancer who is seen face-to-face at the hospital, either as an inpatient or an outpatient, who is assigned a hospital or outpatient clinic number, and who fulfills the additional above criteria.

A similar definition prevails in the case of a center made up of several affiliated institutions. Here the key criterion, however, is whether agreements with the affiliates are sufficiently strong so as to guarantee that all their cancer patients will be reported to the center's registry and followed up. This would usually be the case, for example, with a children's hospital affiliated with a general university hospital, provided that the children's hospital had agreed to submit data on all cancer patients to the center registry. It would not apply to "satellite" institutions which submitted only a portion of their cancer patient population, or to patients whose only contact with the center was by virtue of being enrolled on protocol studies organized among community practitioners by center staff. These latter two patient categories allow too great a degree of selectivity in the type of patient registered.

Therapeutic Trials: Those trials in which an agent is used with the intention of curing, prolonging, or improving the life of the patient with cancer.

National Protocols: Multi-institutional trials in which the center provides leadership or is a participant (i.e. including or equivalent to National Cooperative Group trials).

Local Protocols: Those conducted by the cancer center primarily in its catchment area (i.e. including institutional trials, either exclusive to your center or in collaboration with other centers, industry-sponsored trials, and other externally peer-reviewed trials).

INSTRUCTIONS

1. If desired, you may include a short narrative summarizing information relevant to trial accrual. See the attachment, "Background and Rationale for Trial Accrual" for further instructions.

2. **Provide the total number of reportable patients by anatomical site of cancer for the selected reporting period**, using the above definitions and the category conventions of the ICD-O as provided in the attachment to this section. These figures should reflect the number of **individuals** coming to the cancer center, as opposed to numbers of visits. Do not include any individual more than once. Refer to the Example Format for Summary 3 for the method by which to present this information.

3. **Provide the total number of patients, both inpatients and outpatients, *actively* participating in therapeutic research protocols by site during the selected reporting period.** Patients should be divided according to whether they were entered on national versus local protocols. Refer to the Example Format for Summary 3 for the method by which to present this information. A patient may appear more than once in those instances in which he/she is on more than one therapeutic protocol during the reporting period. Do **not** include patients on non-therapeutic trials.

Background and Rationale for Trial Accrual

(Optional)

In the space below, provide any background information relevant to clinical trials accrual for the selected reporting period. This may include information on changes occurring since the last reporting period that have altered the number of patients accrued, the type of patients accrued, or patterns of accrual across anatomic sites. It may also include information on limitations to accrual, such as institutional barriers or lack of infrastructure, ineligibility of the population served, loss of clinical trials faculty, or other factors. The information presented should be brief.

Summary 3 – Example Format Reportable Patients/Accrual to Therapeutic Protocols	2P30CA654321-50

Outstanding University Cancer Center

reporting period 1/1/2002 – 12/31/2002

Name of Reporting Source		Accrual to Therapeutic Protocols	
Disease Site	Total Patients	National	Local
Lip, Oral Cavity and Pharynx			
Esophagus			
Stomach			
Small Intestine			
Colon			
Rectum			
Anus			
Liver			
Pancreas			
Other Digestive Organ			
Larynx			
Lung			
Other Respiratory and Intrathoracic Organs			
Bones and Joints			
Soft Tissue			
Melanoma, skin			
Kaposi's sarcoma			
Mycosis Fungoides			
Other Skin			
Breast – Female			
Breast – Male			
Cervix			
Corpus Uteri			
Ovary			
Other Female Genital			
Prostate			
Other Male Genital			
Urinary Bladder			
Kidney			
Other Urinary			
Eye and Orbit			
Brain & Nervous System			
Thyroid			
Other Endocrine System			
Non-Hodgkin's Lymphoma			
Hodgkin's Lymphoma			
Multiple Myeloma			
Lymphoid Leukemia			
Myeloid Leukemia			
Monocytic Leukemia			
Leukemia, not otherwise specified			
Other Hematopoietic			

Unknown Sites			
Ill-Defined Sites			
TOTAL:			

International Classification of Diseases for Oncology

ICD-O-3 CODES and Cross References to ICD-9-CM Codes to be used with Summary 3, Patient Information

PRIMARY DISEASE SITE	ICD-9-CM	ICD-O-3
Lip, Oral Cavity and Pharynx	140.0-140.9, 141.0-141.9, 143.0-143.9, 144.0-144.9, 145.0-145.9, 142.0, 142.1-142.9, 146.0-146.9, 147.0-147.9, 148.1, 148.0, 148.2-149.9	C00.0-C00.9, C01.9-C02.9, C03.0-C03.9, C04.0-C04.9, C05.0-C06.9, C07.9, C08.0-C08.9, C09.0-C10.9, C11.0-C11.9, C12.9, C13.0, C13.1-C14.8
Esophagus	150.0-150.9	C15.0-C15.9
Stomach	151.0-151.9	C16.0-C16.9
Small Intestine	152.0-152.9	C17.0-C17.9
Colon	153.0-153.9	C18.0-C18.9
Rectum	154.0-154.1	C19.9, C20.9
Anus	154.2-154.8	C21.0-C21.8
Liver	155.0-155.1	C22.0-C22.1
Pancreas	157.0-157.9	C25.0-C25.9
Other Digestive Organ	156.0-156.9; 159.0-159.9	C23.9, C24.0-C24.9, C26.0-C26.9
Larynx	161.0-161.9	C32.0-C32.9
Lung	162.2-162.9	C34.0-C34.9
Other Respiratory and Intrathoracic Organs	160.0-160.9, 162.0, 163.0-163.9, 164.0-165.9	C30.0-C31.9, C33.9, C37.9, C38.0-C39.9
Bones and Joints	170.0-170.9	C40.0-C41.9
Soft Tissue	171.0-171.9, 158.0-158.9	C47.0-C47.9, C48.0-C48.8, C49.0-C49.9
Melanoma, skin	172.0-172.9	C44.0-C44.9 with M8720-8790
Kaposi's sarcoma	176.0-176.9	M9140
Mycosis Fungoides	202.1-202.2	M9700-9701
Other Skin	173.0-173.9	C44.0-C44.9
Breast - Female	174.0-174.9	C50.0-C50.9
Breast – Male	175.0, 175.9	C50.0-C50.9
Cervix	180.0-180.9	C53.0-C53.9
Corpus Uteri	182.0-182.8, 179	C54.0-C54.9, C55.9

Ovary	183.0	C56.9
Other Female Genital	181, 183.2-184.9	C51.0-C52.9, C57.0-C57.9, C58.9
Prostate	185	C61.9
Other Male Genital	186.0-187.9	C60.0-C60-9, C62.0-C63.9
Urinary Bladder	188.0-188.9	C67.0-C67.9
Kidney	189.0-189.1	C64.9, C65.9
Other Urinary	189.2-189.9	C66.9, C68.0-C68.9
Eye and Orbit	190.0-190.9	C69.0-C69.9
Brain and Nervous System	191.0-192.9	C70.0-C72.9
Thyroid	193	C73.9
Other Endocrine System	194.0-194.9	C74.0-C75.9
Non-Hodgkin's Lymphoma	200.0-200.8, 202.0,202.8	M9590-9591, M9596, M9670-9699, M9702-9709, M9714-9719, M9727-9729
Hodgkin's Lymphoma	201.0-201.9	M9650-9667
Multiple Myeloma	203.0, 203.1	M9732, M9733
Lymphoid Leukemia	204.0-204.9	C42.1 with M9820-9837
Myeloid and Monocytic Leukemia	205.0-205.9, 206.0-206.9	C42.1 with M9840-9931
Leukemia, other	202.4, 2070-2078	C42.1 with M9940-9948, M9734, M9742
Leukemia, not otherwise specified	208.0-208.9	C42.1 with M9800- M9805
Other Hematopoietic	202.3, 202.5-202.6, 202.9, 203.8, 238.6-238.7	C42.0-C42.4, C77.0-C77.9 M9731, M9760, M9761-9764, M9740-9741, M9750-9758, M9950-9964, M9980-9989
Unknown Sites	199.0-199.1	C80.9
Ill-Defined Sites	195.0-195.8	C76.0-C76.8

SUMMARY 4
Clinical Research Protocol Information

INSTRUCTIONS

Use the example format for Summary 4 as a guide to produce a report of the open protocols at your cancer center. Do not include protocols that were not open to accrual during the reporting period.

1. **Provide the following information in the heading (top of each page) of your report:**

   - **Name of Institution:** Provide data for the active protocols at the primary research hospital or treatment facility under the direct governance of the cancer center. If there is more than one primary research hospital or treatment facility associated with the center, or if affiliated institutions contribute to the study, patient accrual by those facilities should be reported in separate columns. Instructions are provided in "Accrual Sites" below.

   - **Reporting period:** Define the 12-month period for which data are being provided. This period should be the same as for other summaries, as indicated in General Instructions.

2. **Divide your report into two sections**: a) those trials involving an agent or device, and b) those trials involving other types of interventions (i.e. behavioral modification, nutritional protocols, etc.). Companion, ancillary or correlative studies associated with a clinical trial should be reported in the same section as that trial. Within each of these two sections, provide only the information requested below. **Do not include epidemiologic or other observational studies.**

3. **The main body of each section (see item 2, above) of your report should be organized into four separate categories**. Identify each of the four categories as follows:

   - **National Cooperative Group Trials** (Place an asterisk [*] next to any trials authored by an investigator at your institution.)

   - **Other Externally Peer-Reviewed Trials** (R01s and P01s funded by NIH or trials supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc.)

   - **Institutional Trials** (In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an institutional investigator at another center. Place an asterisk [*] next to any multi-site trials authored by an investigator at your institution.)

   - **Industrial Trials** (Design and implementation of the study is controlled by the pharmaceutical company)

4. Within each of the four categories described above, provide a column in your report, in the order provided, for each of the details listed below:

- **Group/Sponsor:** Provide the name of the cooperative group or other external sponsor. For national groups use CALGB, CCG, ECOG, GOG, NSABP, POG, RTOG, SWOG. For externally peer-reviewed trials, list the funding agency. For industrial trials, **list the name of the pharmaceutical company** that is sponsoring the trial. For institutional trials, list the names of the applicable funding agencies, including the parent institution, pharmaceutical company, or in the case of a multi-site trial, the name of the other sponsoring cancer center.

- **Anatomic Site (Site):** Identify the name of anatomic cancer site(s) (i.e. breast, ovary) on which the trial is focused, using the Summary 3, Attachment 2 ICD-O list. Up to three anatomic sites may be listed. If a feasibility or early phase trial is broadly applicable to a number of potential anatomic sites, indicate either the most likely anatomic site for an initial trial; if that has not been determined, enter the term "multiple" in this column.

- **Protocol ID:** Provide the unique identifier for this study. For both national and externally reviewed trials, list the common protocol number that the trial is known under nationally (if one exists) - not an internal institutional number. For both institutional and industrial trials, an internal protocol identification number or IRB number is acceptable.

- **Principal Investigator (PI):** Provide the **last name, and first initial** of the Principal Investigator from your center who is responsible for this study.

- **Program (Prog):** Provide the program name or program code at your center that this protocol is related to. **Use the codes defined in Summary 1.** You may omit this column if all protocols at your center are conducted under one program.

- **Date Opened:** Provide the date that this protocol was opened to accrual at your center.

- **Date Closed:** If the study was closed to accrual at your center during the 12-month reporting period, provide the date it was closed.

- **Phase:** Provide the phase that this trial is in. **Acceptable phases are Pilot/Feasibility, I, I/II, II, II/III, III, III/IV, IV, IV/V, V. For ancillary or correlative studies, indicate "N/A."**

- **Trial Type (Type):** Identify the type of trial, according to the following categories: **Screening, Early Detection, or Diagnostic** (trials directly testing the efficacy of devices, techniques, procedures, or tests for earlier/more accurate detection or diagnosis of disease); **Therapeutic** (trials in which an agent or other intervention is used with the intention to cure, prolong, or improve the life of the patient), **Prevention** (studies in which an agent or other intervention is used to prevent cancer or its recurrence); **Ancillary or Companion** (auxiliary studies that are

stimulated by, but not a required part of, a main clinical trial, and that utilize patient or other resources of the main trial to generate information relevant to it), and **Correlative** (laboratory based studies using trial-related specimens to assess cancer risk, clinical outcomes, response to therapies, etc.). Any companion, ancillary, or correlative study included must be linked to an active trial (screening, early detection, diagnostic; therapeutic; or prevention) and include only patients accrued to that trial.

- **Title:** Provide a concise title for this trial. Please limit it to 100 characters.

- **Target:** Indicate the total number of patients needed for the entire study (i.e. the targeted accrual) as stated in the protocol. Do **not** submit a targeted range, such as "10 – 100." If this is a national trial, cite only the number of patients the cancer center expects to accrue over the next 12 months of the reporting period. If the center is a **participant** in a multi-site trial that was initiated by an investigator at another institution, enter only the number of patients to be accrued by the center during the next 12 months of the reporting period. If the center **initiated** the multi-site trial, enter both the number of patients needed for the entire study across all participating sites (in parentheses), and the number of patients to be accrued by the center during the next 12 months of the reporting period.

- **Accrual Site:**

  - Cancer Center (Primary)**:** Create a patient accrual reporting column for patients treated at the primary hospital or treatment facility of the cancer center (one source only).

  - Other (optional): Create a separate patient accrual reporting column for each additional hospital or treatment facility closely associated with the cancer center (e.g., VA, Children's Hospital, other teaching hospital).

  - Affiliates Combined (optional): Centers that have hospital affiliates or private practitioners entering patients to center trials may wish to include a patient accrual reporting column to show the number of patients accrued collectively by the affiliates. This information is useful in understanding the breadth of the center's clinical trials activity; however, reporting this data here is entirely optional.

  - Totals (optional): Create a "Totals" column for summing patient accruals from the "Cancer Center (Primary)", "Other", and "Affiliates" columns. If only data for the "Cancer Center Primary" are provided, a "Totals" column for summing accruals is not necessary.

- **Accrual Timeframes:**

  - 12 Mos**:** For each accrual site reporting column, provide a count of the number of patients that were accrued to this trial during the identified 12-month reporting period. For centers that report accrual from other sources, sum the "12 Mos" accrual for all columns and provide the result in the appropriate subcategory under the "Totals" column.

  - To Date**:** For each accrual site reporting column, provide a count of the

number of patients accrued to this trial to date. This is a cumulative figure, not an annual total. For centers that report accrual from other sources, sum the "To Date" accrual for all columns and provide the result in the appropriate subcategory under the "Totals" column.

5. Sort the report in the following order (see sample format):

    a. Section (see item 2 above)
    b. Category of trial (see categories listed in item 3 above)
    c. Research Program (see research program in item 4 above)
    d. Principal Investigator (see Principal Investigator in item 4 above)

Outstanding University Cancer Center

reporting period 1/1/2002 - 12/31/2002

SECTION 1 (Agent or Device)
NATIONAL

											ACCRUAL							
Sponsor	**Site**	**Proto ID**	**PI**	**Prog**	**Date Opened**	**Date Closed**	**Phase**	**Type**	**Title**	**Target**	**Ctr 12 mos**	**Ctr To Date**	**Oth 12 mos**	**Oth To Date**	**Aff 12 mos**	**Aff To Date**	**Tot 12 mos**	**Tot To Date**
ECOG	Bladder	9638	Saperstein, R.*	2	1/17/99		II	Treat	Study of Paclitaxel plus Carboplatin in Patients with Advanced Carcinoma of the Bladder	4	1	1	0	1	0	0	1	2
POG	Soft	D9902	Schubert, W.	3	1/24/01		N/A	Ancil	Children's group protocol for collecting and banking soft tissue sarcoma specimens	25	5	10	4	4	0	1	9	15
GOG	Cervix	106	Smith, J.	3	1/25/00		II	Treat	Evaluation of Gemcitabine in Persistent or Recurrent Non-Squamous Cell Carcinoma of the Cervix	2	0	1	0	1	0	0	0	2

EXTERNALLY PEER-REVIEWED

Sponsor	**Site**	**Proto ID**	**PI**	**Prog**	**Date Opened**	**Date Closed**	**Phase**	**Trial Type**	**Title**	**Target**	**Ctr 12 mos**	**Ctr To Date**	**Oth 12 mos**	**Oth To Date**	**Aff 12 mos**	**Aff To Date**	**Tot 12 mos**	**Tot To Date**
NCI	Melanoma	9971	Ryabinsky, D.	4	9/24/02		N/A	Corr	Detection of melanoma specific markers in the peripheral blood of pts with stage III or IV melanoma	50	15	15	10	10	0	0	25	25

INSTITUTIONAL

Sponsor	**Site**	**Proto ID**	**PI**	**Prog**	**Date Opened**	**Date Closed**	**Phase**	**Trial Type**	**Title**	**Target**	**Ctr 12 mos**	**Ctr To Date**	**Oth 12 mos**	**Oth To Date**	**Aff 12 mos**	**Aff To Date**	**Tot 12 mos**	**Tot To Date**
OUCC	Multiple	02-010	Booker, M	3	6/9/01		I	Treat	Ph I trial of subcutaneous and/or oral calciriol [(1,25-COH)2D3] and Carboplatin in advanced solid tumors	100	12	30	5	22	10	25	27	77
OUCC	Ovary	U12001	Davis, A	5	4/3/00		N/A	Ancil	Vasculogenic Mimicry	50	8	12	0	0	28	34	36	46

		04872							in Ovarian Cancer										
OUCC	Breast	01-11	Raymond, S.	6	6/2/01		Pilot	Treat	Rescue of mucin specific immune memory as an adjunct to autologous stem cell transplantation for breast cancer	5	0	1	1	1	0	0	1	2

INDUSTRIAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
SuperPharm	Leukemia	SP-990	Gonzalez, R	2	7/3/01		II	Treat	Genasense (Bcl-2 Antisense) Combined with Mylotarg (gemtuzumab ozogamicin) in Elderly Patients with Relapsed Acute Myeloid Leukemia	5	2	2	2	2	2	2	6	6
TechnoCorp	Breast	ID 996	Johnson, H.	2	1/1/01		III	Chemo	TNC400 vs. Placebo for prevention of drug neurotoxicity	15	4	8	2	6	1	3	7	17

SECTION 2 (Non-Agent)
NATIONAL

											ACCRUAL							
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
ECOG	Prostate	CRJ-51	Harshman, A.	2	01/07/95		Pilot	Treat	Randomized pilot study to evaluate whether an outpatient educational and behavioral skills training program will improve pain control in patients who have metastatic or recurrent prostate cancer	225	15	191	19	19	0	0	34	210

EXTERNALLY PEER-REVIEWED

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
NCI	Multi	93-55	Prince, A.	3	3/5/02		N/A	Prev	Teen smoking prevention and cessation via CD ROM program	500	46	210	0	0	95	150	141	360
NCI	Prostate	00-420	Gomez, M.	3	4/20/01		N/A	Treat	Biobehavioral effects of emotional expression in cancer	100	12	53	5	20	2	14	19	87

NIH	Multi	00-037	Blankenship, K.	3	5/8/02		N/A	Treat	An intervention to improve end-of-life pain	90	12	12	6	6	4	4	22	22
NCI	Esophagus	99-315	Shepard, R.	3	3/1/99		N/A	Prev	Smoking cessation intervention for head and neck cancer patients	260	120	221	20	35	18	55	158	311
Susan G. Komen	Breast		Greenberg, S.	3	2/10/99		N/A	Treat	Family Caregiver Interventions	65	0	0	0	0	32	46	32	46
NCI	Breast	95-41	Michaels, L.	3	6/1/95		N/A	Treat	Women's Intervention Nutrition Study (WINS)	N/A	0	90	0	0	10	95	10	185
NCI	Multi	00-4011	Farrell, W.	3	4/25/01		N/A	Prev	Exercise intervention in colorectal polyp patients	300	22	76	65	103	6	30	71	133
Army	Cervix	38552	Garner, F.	3	4/1/99		N/A	Diag	An intervention to improve screening behavior in women at high risk of cervix cancer	140	0	49	0	0	4	31	4	80

INSTITUTIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
OUCC	Lip, Oral Cavity	3929	Collyer, E.	3	9/7/00		N/A	Treat	Biobehavioral interventions for oral pain	70	13	13	6	23	0	0	19	36
OUCC	Breast	17-97	*Guralnick, C.	3	10/3/99		N/A	Treat	An exercise intervention program for cancer patients	115	6	74	2	10	4	42	12	126

INDUSTRIAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Ctr 12 mos	Ctr To Date	Oth 12 mos	Oth To Date	Aff 12 mos	Aff To Date	Tot 12 mos	Tot To Date
ACS	Multi	7785	Chu, Y.	3	6/7/00		N/A	Treat	Intervention to enhance psychosexual development in adolescents and young adults with cancer	72	10	20	15	30	20	40	45	90

Outstanding University Cancer Center

reporting period 1/1/2002 - 12/31/2002

SECTION 1 (Agent or Device)
NATIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
ECOG	Bladder	9638	*Saperstein, R.	2	1/17/99		II	Treat	Study of Paclitaxel plus Carboplatin in Patients with Advanced Carcinoma of the Bladder	4	0	4
POG	Soft	D9902	Schubert, W.	3	1/24/01		N/A	Ancil	Children's group protocol for collecting and banking soft tissue sarcoma specimens	25	1	1
GOG	Cervix	106	Smith, J.	3	1/25/00		II	Treat	Evaluation of Gemcitabine in Persistent or Recurrent Non-Squamous Cell Carcinoma of the Cervix	2	0	0

EXTERNALLY PEER-REVIEWED

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
NCI	Melanoma	9971	Ryabinsky, D.	4	9/24/02		N/A	Corr	Detection of melanoma specific markers in the peripheral blood of pts with stage III or IV melanoma	50	2	8

INSTITUTIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
OUCC	Multiple	02-010	Booker, M	3	6/9/01		I	Treat	Ph I trial of subcutaneous and/or oral calciriol [(1,25-COH)2D3] and Carboplatin in advanced solid tumors	100	16	51
OUCC	Ovary	U1200104872	Davis, A	5	4/3/00		N/A	Ancil	Vasculogenic Mimicry in	50	0	0

									Ovarian Cancer			
OUCC	Breast	01-11	Raymond, S.	6	6/2/01		Pilot	Treat	Rescue of mucin specific immune memory as an adjunct to autologous stem cell transplantation for breast cancer	5	0	4

INDUSTRIAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
SuperPharm	Leukemia	SP-990	Gonzalez, R	2	7/3/01		II	Treat	Genasense (Bcl-2 Antisense) Combined with Mylotarg (gemtuzumab ozogamicin) in Elderly Patients with Relapsed Acute Myeloid Leukemia	5	0	1
TechnoCorp	Breast	ID 996	Johnson, H.	2	1/1/01		III	Chemo	TNC400 vs. Placebo for prevention of drug neurotoxicity:double-blind multicenter random trial ph 3 trial in pts w/ metastatic breast ca	15	0	1

SECTION 2 (Non-Agent)
NATIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
ECOG	Prostate	CRJ-51	Harshman, A.	2	01/07/95		Pilot	Treat	Randomized pilot study to evaluate whether an outpatient educational and behavioral skills training program will improve pain control in patients who have metastatic or recurrent prostate cancer	225	15	191

EXTERNALLY PEER-REVIEWED

NCI	Multi	93-55	Prince, A.	3	3/5/02		N/A	Prev	Teen smoking prevention and cessation via CD ROM program	500	46	210
NCI	Prostate	00-420	Gomez, M.	3	4/20/01		N/A	Treat	Biobehavioral effects of emotional expression in cancer	100	12	53
NIH	Multi	00-037	Blankenship, K.	3	5/8/02		N/A	Treat	An intervention to improve end-of-life pain	90	2	12
NCI	Esophagus	99-315	Shepard, R.	3	3/1/99		N/A	Prev	Smoking cessation intervention for head and neck cancer patients	260	120	221
Susan G.	Breast		Greenberg, S.	3	2/10/99		N/A	Treat	Family Caregiver	65	0	0

Komen									Interventions			
NCI	Breast	95-41	Michaels, L.	3	6/1/95		N/A	Treat	Women's Intervention Nutrition Study (WINS)	N/A	0	90
NCI	Multi	00-4011	Farrell, W.	3	4/25/01		N/A	Prev	Exercise intervention in colorectal polyp patients	300	22	76
Army	Cervix	38552	Garner, F.	3	4/1/99		N/A	Diag	An intervention to improve screening behavior in women at high risk of cervix cancer	140	0	49

INSTITUTIONAL

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
OUCC	Lip, Oral Cavity	3929	Collyer, E.	3	9/7/00		N/A	Treat	Biobehavioral interventions for oral pain	70	13	13
OUCC	Breast	17-97	*Guralnick, C.	3	10/3/99		N/A	Treat	An exercise intervention program for cancer patients	115	6	74

INDUSTRY

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Trial Type	Title	Target	Accrual 12 Mos	Accrual To Date
ACS	Multi	7785	Chu, Y.	3	6/7/00		N/A	Treat	Intervention to enhance psychosexual development in adolescents and young adults with cancer	72	0	0

SUMMARY 5
Summary and Comparison of Current and Requested CCSG Budgets

INSTRUCTIONS

Peer reviewers have requested a comparison of the current CCSG budget to the first year requested budget in the renewal application. Using the attached format as a guide, provide the current CCSG budget (middle column), and the requested budget for the first year of the renewal application (right column) for each major budget category listed on the left. List the shared resources individually, as shown in the examples. Developmental funds may be further subcategorized into recruitments, interim support, pilot projects, and new shared resources, if desired. Show a sum of the total direct costs at the bottom of the chart.

The current budget, including the budget for each category and total direct costs, should reflect the last full year of the current competitive segment as submitted in the type 5 application and/or as detailed in the notice of award for that period, exclusive of carryover funds and supplements. The direct cost figures should include any third party indirect costs, since these are charged as direct costs to the CCSG.

Summary 5 – Example Format 2P30CA654321-50

Summary and Comparison of Current and Requested CCSG Budgets

Outstanding University Cancer Center

CCSG BUDGET CATEGORY	*DIRECT COSTS* CURRENT BUDGET * *[insert date e.g., 01/01/00 – 12/31/00]* LAST (FULL) YEAR OF CURRENT COMPETITIVE SEGMENT	*DIRECT COSTS* REQUESTED BUDGET *[insert date e.g., 01/01/01 – 12/31/01]* FIRST YEAR OF COMPETITIVE RENEWAL APPLICATION
PROFESSIONAL PERSONNEL Senior Leadership Major Program Directors Staff Investigators Subtotal ADMINISTRATION PLANNING & EVALUATION SHARED RESOURCES & SERVICES Examples: Animal Facility Flow Cytometry Shared Resource Electron Microscope Shared Resource Etc. Subtotal PROTOCOL REVIEW AND MONITORING SYSTEM PROTOCOL -SPECIFIC RESEARCH SUPPORT DEVELOPMENTAL FUNDS		
TOTAL DIRECT COSTS		

***Exclusive of Carryover Funds and Supplements and inclusive of third party indirect cost**